

REMARKS

This is in response to the Final Office Action of August 18, 2008. Claims 1-6 are pending in the present application, and claims 7-18 are new. Claims 1, 7 and 13 are independent. This response is being filed with a Request for Continued Examination and a Supplemental Information Disclosure Statement.

In the Office Action, the Examiner: (1) rejected claims 1-6 under 35 USC 103 as being unpatentable over US 5,954,971 to Pages et al. in view of US 5,350,357 to Kamen et al. and further in view of US 4,750,868 to Lundback.

Claims 1-6 Would Not Have Been Obvious

In response to the rejection of claims 1-6 under 35 USC § 103, Applicants have amended independent claim 1 and the respective dependent claims to further define the claimed subject matter. In particular, claim 1 has been amended to recite a "fluid processing system", and the feature of a filter has been deleted. Further, Applicants have specifically recited that each of the first and second fluid pressure actuated pump stations comprises a separate fluid inlet and a separate fluid outlet. Applicants submit that the amendments to claims 1-6 are fully supported by the application specification as originally filed and do not add new matter. See, for example, pg. 4, para. [0083] and Fig. 7 and pg. 34, paras. [0528]-[0531] of the published application, for example. It is respectfully submitted that amended independent claim 1 and the respective dependent claims would not have been obvious over the cited references.

Specifically, amended independent claim 1 requires, among other things, a fluid processing system comprising first and second fluid pressure actuated pump stations, wherein each of said first and second fluid pressure actuated pump stations comprises a separate fluid inlet and a separate fluid outlet, and a fluid pressure actuator operating to selectively apply fluid pressure pump strokes in tandem to the first and second pump stations to convey fluid from a source to a destination. The fluid pressure actuator includes a control function to switch between a first flow mode, in which the pump strokes draw a fluid volume into the fluid inlet of the first pump station from the source and expel a fluid volume from the fluid outlet of the second pump station to the destination, and a second flow mode, in which the pump strokes draw a fluid volume into the fluid inlet of the second pump station from the source and expel a fluid volume from the fluid outlet of the first pump station to the destination. The control function operates to synchronize the pump strokes so that fluid flow from the source is essentially continuous while fluid flow to the destination is pulsatile.

In contrast, the cited references do not, either alone or in combination, describe or suggest a fluid processing system as presently claimed. Applicants discuss each of the Examiner's objections, in turn, below.

Pages Does Not Describe A Fluid Processing System Comprising
First And Second Fluid Pressure Actuated Pump Stations

Turning first to U.S. Patent 5,954,971 to Pages, Pages does not describe a fluid processing system comprising first and second fluid pressure actuated pump stations wherein each of the first and second fluid pressure actuated pump stations comprises a

separate fluid inlet and a separate fluid outlet as required by amended claim 1. In contrast, Pages discloses a fluid circuit including a peristaltic pump 132 that operates on tubing line 130 to move fluid throughout the system, or similarly, a pair of peristaltic pumps 232a and 232b that operate on tubing line 230. See Pages, col. 3, lines 45-50 and Figure 1 and col. 6, lines 19-22 and Figure 2. Thus, Pages simply does not disclose or even contemplate first and second fluid pressure actuated pump stations as required by amended claim 1.

Pages Does Not Describe A Fluid Processing System In Which A Fluid Pressure Actuator Operates To Selectively Apply Fluid Pressure Actuated Pump Strokes In Tandem To First And Second Pump Stations, And Is Not Properly Combinable With Kamen To Render The Claimed Subject Matter Obvious

Second, Pages does not describe a fluid processing system in which a fluid pressure actuator operates to selectively apply fluid pressure pump strokes in tandem to first and second pump stations to convey fluid from a source to a destination, and the Examiner expressly acknowledges this fact in the Office Action.

While the Examiner expressly acknowledges the lack of disclosure of this claimed feature in Pages, the Examiner then suggests combining the teachings of Pages with Kamen to achieve the claimed subject matter. However, contrary to the Examiner's suggestion, it is respectfully submitted that the Kamen patent is not properly combinable with Pages to render the claimed subject matter obvious. In particular, even if one were to make the unlikely combination of the dialysis system disclosed in Kamen

with the blood processing system described in Pages, the resulting device would still not have the features of the claimed fluid processing system.

In particular, when determining whether the claimed invention would have been obvious under §103, a prior art reference must be considered in its entirety, including disclosures that teach away from the claims. W. L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 1550 (Fed. Cir. 1983). Also see M.P.E.P. 2141.21 (VI). In this regard, the Examiner has cited the Kamen reference and suggested that it teaches the claimed feature of an actuator operating pump strokes in tandem to first and second pump stations. However, when considered in its entirety, it expressly teaches away from the pending claim requirement of an actuator including a control function to synchronize pump strokes so that fluid flow from a source is essentially continuous while fluid flow to a destination is pulsatile. In fact, Kamen actually teaches the opposite. For example, Kamen specifically teaches that pump chambers P1 and P2 operate to provide continuous, not pulsatile, flow. In particular, Kamen describes a dialysis system including a cassette with pump chambers P1 and P2, which pump in a sequence such that heated dialysate is always introduced into the pump chambers P1 and P2 while heated dialysate is always discharged through the pump chambers P1 and P2 to the patient. See Kamen, col. 32, lines 6-10. Thus, fluid flow into and from pump chambers P1 and P2 is essentially continuous. This would be contrary to the claimed fluid processing system which requires a control function that synchronizes pump strokes so that fluid flow to a destination is pulsatile, as set forth in amended claim 1.

Thus, while the Examiner has cited Kamen as allegedly describing operating first and second pump stations in tandem, it actually teaches away from another claimed feature. Kamen, therefore, is not properly combinable with Pages for at least the reason that it is improper to combine references that teach away from the claimed invention. See M.P.E.P. 2145(X). For at least this reason, it is respectfully submitted that it would not have been obvious to one skilled in the art to combine Pages with Kamen to reach the present invention.

Pages Does Not Describe A Fluid Pressure Actuator Including
A Control Function To Switch Between A First Mode and A Second Mode

Third, Pages does not describe a fluid pressure actuator that includes a control function to switch between a first flow mode, in which the pump strokes draw a fluid volume into the fluid inlet of the first pump station from the source and expel a fluid volume from the fluid outlet of the second pump station to the destination, and a second flow mode, in which the pump strokes draw a fluid volume into the fluid inlet of the second pump station from the source and expel a fluid volume from the fluid outlet of the first pump station to the destination, as required by claim 1. For example, as described in further detail in the specification of the present application, the fluid pressure actuator switches between a first and second flow mode, allowing, for example, pump stations PP3 and PP4 to "toggle" or alternate draw and expel functions. See page 34, para. [0531].

It is respectfully submitted that the above-described claimed feature is not found nor contemplated in Pages. While Pages describes a draw cycle in which whole blood

drawn from a donor is centrifuged into its components and passed through a filter, and also describes operating the cycle a second time, if necessary, to process a particular volume of blood or components, each of these cycles operates fully and independently from one another. See col. 8, lines 19-25 of Pages which describes that "when the centrifuge bowl 210 is emptied or the predetermined volume of product processed, apparatus 200 begins a second draw cycle identical to that [first cycle] described above." Thus, only when an "first" draw cycle is complete can the "second" cycle begin. No matter how the system in Pages is programmed or what processing procedure is intended to be performed, Pages does not describe a fluid pressure actuator including a control function as presently claimed, nor is Pages even capable of switching between a first flow mode, in which the pump strokes draw a fluid volume into the fluid inlet of the first pump station from the source and expel a fluid volume from the fluid outlet of the second pump station to the destination, and a second flow mode, in which the pump strokes draw a fluid volume into the fluid inlet of the second pump station from the source and expel a fluid volume from the fluid outlet of the first pump station to the destination as required by claim 1.

**Pages Does Not Describe A Fluid Pressure Actuator That Synchronizes Pump Strokes
So That Fluid Flow From The Source Is Continuous While Fluid Flow
To The Destination Is Pulsatile, And Is Not Properly Combinable
With Lundback To Render The Claimed Subject Matter Obvious**

Fourth, Pages does not describe a control function operating to synchronize pump strokes so that fluid flow from a source is essentially continuous while fluid flow to a destination is pulsatile, and the Examiner expressly acknowledges this fact in the

Office Action. Further, Lundback is not properly combinable with Pages to render the claimed subject matter obvious.

As noted above, Pages does not describe various structural features as set forth in the pending claims and, as acknowledged in the Office Action, Pages does not disclose a fluid pressure actuator including a control function that synchronizes pump strokes so that fluid flow from a source is essentially continuous while fluid flow to a destination is pulsatile. Further, even if one were to combine Pages with the Lundback pump, the result would still not have the features of the claimed fluid processing system for several reasons.

First, Lundback does not describe a fluid processing system comprising first and second fluid pressure actuated pump stations wherein each of the first and second fluid pressure actuated pump stations comprises a separate fluid inlet and a separate fluid outlet as presently claimed. Instead, Lundback describes generally only a *single* pump having a *single* inlet and a *single* outlet that can be used in industry, mining, and the like. In the Office Action, it appears that the Office considers pump chambers “A” and “V” of Lundback to be comparable to the claimed “first and second fluid pressure actuated pump stations”. However, pump chambers “A” and “V” of Lundback communicate with only one inlet and one outlet—that is, there is a single inlet and a single outlet through which fluid enters and exits the Lundback pump. Thus, Lundback does not describe or even contemplate first and second fluid pressure actuated pump stations that each comprise a separate fluid inlet and a separate fluid outlet as required by amended claim 1.

Second, Lundback does not describe a fluid pressure actuator operating to selectively apply fluid pressure pump strokes in tandem to first and second pump stations, the fluid pressure actuator including a control function to switch between a first flow mode, in which the pump strokes draw a fluid volume into the fluid inlet of the first pump station from the source and expel a fluid volume from the fluid outlet of the second pump station to the destination, and a second flow mode, in which the pump strokes draw a fluid volume into the fluid inlet of the second pump station from the source and expel a fluid volume from the fluid outlet of the first pump station to the destination. Instead, as already described above, pump chambers "A" and "V" of Lundback communicate with only one inlet and one outlet. Therefore, Lundback does not describe or contemplate a fluid pressure actuator operating to selectively apply fluid pressure pump strokes in tandem to first and second pump stations wherein each of the first and second pump stations comprises a separate fluid inlet and a separate fluid outlet, and further, no matter how the Lundback pump is operated it would not be capable of switching between a first and second flow mode in which pump strokes draw a fluid volume into separate fluid inlets of first and second pump stations and expel fluid from separate fluid outlets of first and second pump stations, respectively, as set forth in amended claim 1.

Therefore, it is submitted that it would not have been obvious to one skilled in the art to combine the features of the system described in Pages with the single pump having a single inlet and a single outlet as described in Lundback to reach the present invention.

Conclusion Regarding Non-Obviousness

Accordingly, it is respectfully submitted that there is no description or suggestion in Pages of a fluid processing system comprising (1) first and second fluid pressure actuated pump stations wherein each of the first and second fluid pressure actuated pump stations comprises a separate fluid inlet and a separate fluid outlet, (2) a fluid pressure actuator that operates to selectively apply fluid pressure pump strokes in tandem to first and second pump stations to convey fluid from a source to a destination, (3) a fluid pressure actuator that includes a control function to switch between a first flow mode, in which the pump strokes draw a fluid volume into the fluid inlet of the first pump station from the source and expel a fluid volume from the fluid outlet of the second pump station to the destination, and a second flow mode, in which the pump strokes draw a fluid volume into the fluid inlet of the second pump station from the source and expel a fluid volume from the fluid outlet of the first pump station to the destination, or (4) a control function operating to synchronize pump strokes so that fluid flow from a source is essentially continuous while fluid flow to a destination is pulsatile as required by claim 1. Further, neither Kamen nor Lundback describes the subject matter missing from Pages, and are not properly combinable with Pages to achieve the claimed subject matter.

For at least the reasons described above, it is respectfully submitted that amended claims 1-6 would not have been obvious over Pages, either alone or in combination with Kamen and/or Lundback. Accordingly, the withdrawal of the rejections and reconsideration and allowance of the claims are respectfully requested.

New Claims 7-12 and 13-18 Would Not Have Been Obvious Over the Cited References

New claims 7-12 are similar to amended claims 1-6, but recite a “blood processing system” rather than a “fluid processing system”. New claims 13-18 are similar to the blood processing system defined by new claims 7-12, with the additional feature of “a filter for removing leukocytes from blood”.

For the same reasons described above that amended claims 1-6 would not have been obvious over Pages, either alone or in combination with Kamen and/or Lundback (which are incorporated herein by reference), Applicants submit that new independent claims 7 and 13 and the respective dependent claims also would not have been obvious over the cited references.

Specifically, there is no description or suggestion in Pages of a blood processing system comprising (1) first and second fluid pressure actuated pump stations wherein each of the first and second fluid pressure actuated pump stations comprises a separate blood inlet and a separate blood outlet, (2) a fluid pressure actuator that operates to selectively apply fluid pressure pump strokes in tandem to first and second pump stations to convey blood from a source to a destination (or to a filter as recited in claim 13), (3) a fluid pressure actuator that includes a control function to switch between a first flow mode, in which the pump strokes draw a blood volume into the blood inlet of the first pump station from the source and expel a blood volume from the blood outlet of the second pump station to the destination (or to a filter as recited in claim 13), and a second flow mode, in which the pump strokes draw a blood volume into the blood inlet

of the second pump station from the source and expel a blood volume from the blood outlet of the first pump station to the destination (or to a filter as recited in claim 13), or (4) a control function operating to synchronize pump strokes so that blood flow from a source is essentially continuous while blood flow to a destination (or to a filter as recited in claim 13) is pulsatile, as required by the pending claims. Further, neither Kamen nor Lundback describe the subject matter missing from Pages, and are not properly combinable with Pages to achieve the claimed subject matter.

For at least the reasons described above, it is respectfully submitted that new claims 7-12 and 13-18 would not have been obvious over Pages, either alone or in combination with Kamen and/or Lundback. Accordingly, allowance of the claims is respectfully requested.

Supplemental Information Disclosure Statement

Finally, Applicants are submitting a Supplemental Information Disclosure with this response. The Supplemental IDS includes the citation of an Office Action that was mailed on September 4, 2008 in Application Serial No. 11/375,965. The cited Office Action from the '965 application cites claim 1 of the present application in a provisional obviousness-type double patenting rejection of certain claims pending in the '965 application. A copy of the September 4, 2008 Office Action is included with the Supplemental IDS for the Examiner's convenient reference.

Applicants respectfully request that the Office Action cited in the Supplemental Information Disclosure statement be considered.

Respectfully submitted,

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